

Health Promotion Programs for Persons with Serious Mental Illness: What Works?

*A Systematic Review and Analysis of the
Evidence Base in Published Research Literature on
Exercise and Nutrition Programs*

Prepared for:

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Jointly-funded by the Substance Abuse and Mental Health Services Administration and the Health Resources and Services Administration, and run by the National Council for Community Behavioral Healthcare, CIHS provides training and technical assistance to 64 community behavioral health organizations that collectively received more than \$26.2 million in Primary and Behavioral Health Care Integration grants, as well as to community health centers and other primary care and behavioral health organizations.

CIHS’ wide array of training and technical assistance helps improve the effectiveness, efficiency, and sustainability of integrated services, which ultimately improves the health and wellness of individuals living with behavioral health disorders.

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Summary

Obesity and sedentary behavior are major risk factors for cardiovascular disease, diabetes, and reduced life expectancy. Over 42% of adults with a serious mental illness are obese, fewer than 20% of people with schizophrenia engage in regular moderate exercise, and people with schizophrenia consume fewer fruits and vegetables and more calories and saturated fats than the general population. A large body of research on the general population supports the benefits of weight loss and fitness interventions on improving health outcomes and longevity. A 5% or greater weight loss for overweight or obese individuals is considered clinically significant, resulting in reduced risk factors for metabolic disorders and cardiovascular disease. In addition, improving cardiorespiratory fitness by just one metabolic equivalent per day* is associated with a reduced mortality risk of 10-17%, independent of weight loss. A limited but growing amount of research has studied the effectiveness of health promotion programs for people with serious mental illness aimed at addressing obesity and improving physical fitness. It is important to note that improving cardiorespiratory fitness has substantial health benefits independent of weight loss.

Objectives

Based on analysis of the aggregate findings from published research literature addressing non-pharmacological lifestyle interventions aimed at reducing obesity and improving fitness for persons with serious mental illness, the Dartmouth Health Promotion Research Team makes specific recommendations on the core components of health promotion interventions and the approaches most likely to be associated with reducing weight, improving physical fitness, and improving psychological symptoms and overall health. This whitepaper provides foundational guidance on the principles of evidence-based and effective health promotion interventions, as well as a balanced assessment of the relative effectiveness and magnitude of health outcomes that can be anticipated.

Methodology

The Dartmouth Health Promotion Research Team reviewed the published research literature addressing non-pharmacological lifestyle interventions aimed at reducing obesity and improving fitness for persons with serious mental illness. The initial search identified 728 articles, which were screened for content, resulting in 52 articles specifically addressing the topic area. From this set, 6 systematic review articles and 24 research trials met predetermined criteria for quality, including 12 randomized controlled trials, six comparison studies and six pre-post outcome studies. The majority of the trials incorporated both nutritional and exercise components into their interventions, although several studies focused on either nutrition or exercise alone. Interventions were characterized according to whether they provided an educational approach, an activity-based approach, or combined education and activity.

* The amount of oxygen required while sitting very quietly at rest.

Results

Intervention participants in 92% of the studies reviewed experienced an overall mean weight loss and/or decrease in body mass index (BMI). Mean weight loss achieved for the interventions studied in the randomized control trials consisted of a median 2.5 kg (5.5 lbs). Change in weight comparing the intervention and control groups was statistically significant in slightly over half (55% or 10 out of 18) of the controlled studies. The median percent of total body weight loss was 2.6% in the 19 research trials providing data. None of the community-based studies achieved a mean or median clinically significant weight loss of 5% or greater. However, some studies reported clinically significant weight loss for a portion of their participants. For example, one of the studies reported that almost two-fifths of participants (38%) lost at least 5% of their baseline weight.

Conclusion

Lifestyle interventions appear to be inconsistently successful in achieving clinically significant weight loss for overweight persons with serious mental illness, and when successful, result in clinically significant weight loss for a minority of participants. To date, it is not known why some individuals participating in lifestyle interventions achieve significant weight loss, and others do not. However, there are characteristics of programs that tend to have greater success than others do. These included program duration and design. For example, research shows programs to have enhanced success if they last three months or longer and incorporate both education and activity-based approaches.

Executive Summary

People with serious mental illnesses (SMI) are at risk of premature death, largely due to cardiovascular and metabolic disorders associated with obesity, sedentary lifestyle, and smoking. Until very recently, mental health services have neglected prevention and health promotion as a core service need for people with SMI.

A Dartmouth research team reviewed the published research literature addressing non-pharmacological lifestyle interventions aimed at reducing obesity and improving fitness for persons with SMI. This comprehensive review underscores the limitations of the existing research literature with respect to the size and quality of most of the existing studies and the modest magnitude of the results with respect to effectiveness. Considering these limitations, this review suggests the following summary findings and recommendations:

Program format: Health promotion programs of longer duration (3 or more months), combining a manualized education- and activity-based approach, and incorporating both nutrition and physical exercise, are likely to be the most effective in reducing weight and improving physical fitness, psychological symptoms, and overall health.

Programs that are less likely to be successful include briefer duration interventions; general wellness, health promotion or education-only programs; non-intensive, unstructured, or non-manualized interventions; and programs limited to nutrition only or exercise only (as opposed to combined nutrition and exercise).

Weight management: If weight loss is a primary goal, the nutritional component is critical and is more likely to be successful if it incorporates active weight management (i.e., participant and program monitoring of weight and food diaries), as opposed to nutrition education alone.

Physical fitness: If physical fitness is a primary goal, activity-based programs that provide intensive exercise and measurement of fitness (e.g., 6-minute walk test or standardized physical activity monitoring) are more likely to be successful, in contrast to programs solely providing education, encouragement, or support for engaging in physical activity.

Integrated services: Evidence-based health promotion consisting of combined physical fitness and nutrition programs should be an integrated component of services seeking to provide overall wellness and recovery for persons with SMI.

Measurement and monitoring: Lifestyle behaviors (nutrition, physical activity, tobacco use), physical fitness, and weight outcomes as well as evidence-based program fidelity should be objectively and reliably measured and monitored both as a component of providing effective health promotion programming *and* as core indicator of quality mental health services.

Methodology

An electronic database search was conducted to identify high quality research studies based on pre-designated inclusion and exclusion criteria. The initial search identified 728 articles that were screened for content, resulting in 52 articles specifically addressing the topic area. From this set, 6 systematic review articles and 24 research trial studies met predetermined criteria for quality, including 12 randomized controlled trial (RCT) studies, 6 comparison studies, and 6 pre-post outcome studies. The majority of the trials incorporated both nutritional and exercise components into their interventions, although several studies focused on either nutrition or exercise. Interventions were characterized according to whether they provided an educational approach, an activity-based approach, or combined education and activity.

Weight loss achieved for the interventions studied in the RCT studies consisted of a median 2.5 kg (5.5 lbs). All of the controlled studies reported differences in weight and/or BMI change between the intervention and control groups, and those differences were statistically significant in 10 of the controlled studies. Intervention group participants achieved a mean weight loss or reduction in BMI in 22 of the 24 studies selected for this review. Percentage weight loss was reported (or able to be calculated) in 19 of the research trials, with a median of 2.6%. Only one study achieved a clinically significant median weight loss of 5% or greater (5.4%), although one other study reported that a significant proportion of participants (38%) lost at least 5% of their baseline weight. Clinically significant increases in physical fitness (as measured by the 6-minute walk test) were achieved in several of the trials. Statistically significant health benefits were reported more frequently among the interventions that utilized a combined educational- and activity-based approach than among those that used one or the other alone. Finally, lifestyle interventions demonstrated improved psychological functioning of people with SMI: over half of the studies that measured depression symptoms reported statistically significant symptomatic improvement from the beginning until the end of the intervention among program participants.

Limitations

There are limitations that should be considered in interpreting and applying the results of this review.

First, the majority of studies reviewed are relatively small study samples and were highly variable in quality. In addition, the majority of studies focused on short-term outcomes and do not evaluate long-term sustainability of health behavior changes and physical measures of weight loss or fitness.

Second, the findings reported here are limited by the methods used to analyze and report outcomes. Numerous important questions are unable to be addressed because of the aggregate approaches used in reporting the results. For example, outcomes were not reported with respect to possible differences in weight loss or improved fitness relative to gender, race, diagnosis, or other important individual factors.

A third limitation of the majority of studies reviewed is the reporting of weight loss outcomes as mean or median weight loss across the entire sample without reporting on the proportion of individuals achieving clinically significant (5% or greater) weight loss or weight gain. This is important, as weight loss interventions in the general population are associated with variability in treatment response across indi-

viduals. The potential value of an intervention in achieving clinically significant weight loss for a portion of the population may be obscured by reporting the overall average weight loss that also incorporates outliers who have gained significant weight for individual reasons or due to lack of adherence to the recommended program.

Fourth, with few exceptions, findings reported in these studies emphasized statistical significance but did not interpret their results with respect to actual clinical or accepted parameters on likely impact on health outcomes.

Fifth, most studies do not account for the effect of different medications with varying degrees of weight gain propensity in their analyses.

Sixth, very few studies systematically evaluated physical fitness with respect to cardiorespiratory status that is an important predictor of health independent of weight.

Seventh, there is a lack of information provided with respect to manuals, training materials, and actual implementations of these models by usual care providers in usual systems of care beyond the reported research study.

Finally, we developed summary conclusions on what are likely to be the most effective characteristics and components of successful programs based on comprehensive assessments of each individual study's available descriptions and the associated magnitude of reported outcomes. However, there are no head-to-head comparisons of these approaches or models in existing literature to definitively determine which approaches are superior. Furthermore, descriptions of the actual components and elements of each intervention were highly variable with respect to detail and intensity of the model delivery.

In summary, the conclusions provided in this systematic review should be considered in the context of these limitations that warrant further research and outcome evaluations in applied usual care settings.

Overview

This white paper provides extensive documentation of high-quality research studies including data on the effectiveness and outcomes of different approaches and models of non-pharmacological lifestyle interventions aimed at reducing obesity and improving fitness for persons with SMI. Based on analysis of the aggregate findings we have made specific recommendations on the core components of health promotion interventions and the approaches that are most likely to be associated with reducing weight, improving physical fitness, and improving psychological symptoms and overall health. This white paper should provide foundational guidance on the principles of evidence-based and effective health promotion interventions, as well as balanced assessment of the relative effectiveness and magnitude of health outcomes that can be anticipated.

This review and analysis is unique in several ways. We have included randomized controlled trial studies as well as well designed, high-quality nonrandomized comparison studies and high-quality nonrandomized pre-post outcome studies. Second, we have analyzed the outcomes for both statistical and clinical significance. Third, we have analyzed the outcomes for different approaches and types of interventions including educational approaches, activity-based approaches, dietary or nutritional interventions, exercise and physical activity interventions, and a combination of these approaches when delivered concurrently. Fourth, we have examined different outcomes beyond weight reduction including physical fitness, psychological improvement, and overall health status improvement. Finally, we have summarized the practical synthesis of the findings and a related set of recommendations for practical use by providers and systems of care. In addition, we identify areas where further research is indicated.

Introduction

Approximately 3% of American adults have a serious mental illness (SMI), including 1% with schizophrenia [1]. The life expectancy of persons with SMI, including schizophrenia, schizoaffective disorder, bipolar disorder and treatment refractory depression, is an alarming shorter than that of the general population [2, 3]. The leading cause of death in this population is cardiovascular disease associated with modifiable health behaviors, including obesity, poor dietary habits, sedentary lifestyle, and smoking. These risk factors combine with the metabolic side effects of some commonly prescribed antipsychotic medications to produce high rates of diabetes, heart disease, and obesity in persons with SMI [4-8]. Moreover, persons with SMI receive substandard medical care compared to the general population, which may contribute to the higher mortality of this group [3, 9, 10]. The reduced life expectancy for adults with SMI is among the greatest health disparities experienced by any subgroup in the United States.

Obesity is more prevalent among persons with SMI compared to those without SMI (42% vs. 27%) [3, 11] and is significantly associated with severity of health problems [12]. Antipsychotic agents are associated with significant weight gain [3, 13-17], and persons with schizophrenia have a three- to six-fold greater risk of developing metabolic syndrome than persons without a previous psychiatric history [3, 18]. Several atypical antipsychotics are associated with hyperlipidemia and decreased glucose tolerance [19, 20]. Based on the association of atypical antipsychotics with metabolic alterations, guidelines recommend metabolic screening and physical evaluations as part of routine practice in mental health settings [19, 21]. These recommendations emphasize the relationship between medical and mental health problems.

Lifestyle behaviors associated with poor health outcomes, such as a sedentary lifestyle and poor eating habits, have been found to be more prevalent in the population of persons with SMI than the general population [22, 23], as have high levels of poverty. Less than one-fifth of individuals with schizophrenia engage in one or more periods of moderate exercise on a weekly basis and nearly two-fifths are physically inactive [9]. Poor diet also has been documented in persons with schizophrenia, including lower consumption of fruits, vegetables and fiber, and greater consumption of calories, nutrients, and saturated fats compared to the general population [9, 24-26]. These factors may combine with metabolic side effects of antipsychotic medications to produce the high rates of diabetes, heart disease, and obesity found in persons with SMI.

Although poor physical health and obesity are common in people with SMI, conventional services focus on psychiatric symptoms and functioning, and few public sector programs target physical fitness [7, 27, 28]. Despite greater costs and adverse outcomes associated with the combination of mental illness and poor physical health [29-31], little attention has been paid to the development of health promotion interventions designed to address the needs of this high-risk group.

Implementing effective health promotion programs in settings where adults with SMI seek and receive services is critical to lowering the risk associated with preventable medical conditions such as cardiovascular disease and obesity. There is a growing body of research on the effectiveness of health promotion programs for persons with SMI. Intervention strategies include exercise programs, diet-only interventions, and combined exercise and diet programming delivered in a variety of modalities including group-

based programs, individualized sessions, and combined group and individual sessions. The purpose of this review is to provide a critical summary of evidence-based practices for health promotion to inform providers in the selection and implementation of best practices.

Literature Review

A research team conducted a review of studies published in peer-reviewed journals relating to physical health promotion programs for persons with SMI and medical co-morbidities.

Methods

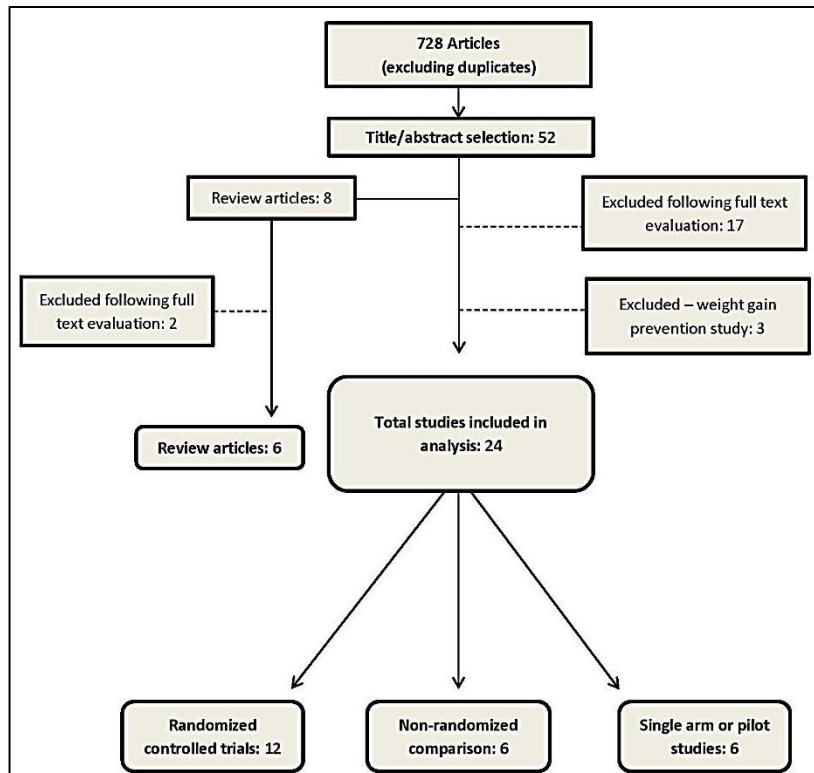
The research team conducted a comprehensive search of published systematic reviews and data-based research studies consisting of the following electronic databases in April 2011: PubMed (MEDLINE), PsycINFO, The Cochrane Library, and CINAHL. Search terms included a combination of keywords and medical subject headings (MeSH) relating to persons with SMI, physical health related co-morbidities, and health promotion interventions. Specifically, the following search parameters were used: ("Schizophrenia"[MeSH] or "Psychotic Disorders"[MeSH] or "Bipolar Disorder"[MeSH] or "Depressive Disorder, Major"[MeSH] or "serious mental illness") AND ("Obesity"[MeSH] or "Diabetes Mellitus"[MeSH] or "Hypertension"[MeSH] or "Heart Failure"[MeSH] or "Hyperlipidemias"[MeSH] or "Myocardial Infarction"[MeSH] or "Comorbidity"[MeSH] or "physical health" or "co-existing" or "co-occurring" or "comorbid") AND ("Health Promotion"[MeSH] or "Diet"[MeSH] or "Diet Therapy"[MeSH] or "Exercise"[MeSH] or "Exercise Therapy"[MeSH] or "Health Behavior"[MeSH] or "Life Style"[MeSH]). Searches were limited to clinical trials, meta-analyses, randomized controlled trial (RCT) studies, and reviews published in the past 20 years, written in the English language and with adult (aged 18+) subjects. In addition, the research team hand selected and/or retrieved relevant articles following full text examination.

Using these search terms, 728 articles were retrieved, screened, and evaluated for relevance. The majority of articles ($n = 676$) were eliminated from consideration based on exclusion criteria or failing to meet inclusion criteria for this review. The 52 remaining articles – including eight literature reviews – satisfied the following inclusion criteria: the trial(s) included a behavioral or educational (non-pharmacological) health promotion intervention with results that used standard measures of physical health outcomes, such as weight, body mass index (BMI), waist circumference, or some other measure of physical fitness; study participants were primarily adults categorized or diagnosed with SMI, including schizophrenia, schizoaffective disorder, bipolar disorder, or severe depression.

The research team conducted a full text systematic examination of the 52 articles (including eight reviews and 44 trials) that fit the inclusion criteria based on initial screening. Of the eight literature reviews that remained following initial screening, one was excluded because it lacked clearly defined inclusion and exclusion criteria, and one was excluded because a subsequent update had been published and included in our final analysis [32, 33]. The final set of review articles that met criteria for this report consisted of six systematic reviews.

Of the 44 research trials, one trial was eliminated because it reported the efficacy results of a trial that subsequently published its final results [34]. Two trials were excluded because a change in physical health was not an intended outcome [35, 36]. One trial was eliminated because neither weight nor BMI were final outcome measures [37].

Figure 1: Process of inclusion and exclusion



Of the remaining 40 studies, 12 consisted of high quality RCTs and 28 consisted of either non-randomized comparison studies or pre-post outcome studies without a comparison group. To control for quality in studies without a randomized design, non-randomized comparison studies or pre-post outcome studies were excluded that: (1) lacked a prospective research design, (2) lacked standardized outcome measures, or (3) had fewer than 30 study participants. Based on these criteria, the research team excluded an additional 13 studies: four single-arm and/or pilot studies lacked a prospective research design [38-41], and nine had fewer than 30 participants [42-50].

Finally, among the remaining 27 studies, three were excluded due to study aims and design intended to prevent weight gain following initiation of an atypical antipsychotic. Although the approaches used were similar to a number of other studies, neither weight loss nor improved fitness was selected as an outcome. While none of the interventions were successful in preventing antipsychotic-induced weight gain, they resulted in lower weight gain among intervention groups when compared to the control groups. In one intervention, participants ($N = 61$) were first assigned to an antipsychotic and then assigned to either a manualized, individualized nutrition- and exercise-based intervention group ($n = 35$) or a usual care group [51]. After the three-month intervention, the intervention group had gained a mean weight of 4.1 kg (9 lbs), while the usual care group had gained 7.0 kg (15.4 lbs), or 2.9 kg (6.4 lbs) more than the intervention group.

A second three-month individualized educational intervention had similar success in preventing weight gain, with the intervention group ($n = 23$) gaining only a mean weight of 2.0 kg (4.4 lbs) and the control group ($n = 11$) gaining 6.0 kg (13.2 lbs) [52].

The third study evaluated the efficacy of a psychoeducational weight gain prevention program for patients treated with olanzapine [53]. This trial had two groups that received the intervention, but one group served as the control group for eight weeks prior to participating in the intervention. In the first eight weeks, the intervention group ($n = 10$) experienced a weight gain of 1.0 kg (2.2 lbs), while the group serving as the control ($n = 8$) gained 3.0 kg (6.6 lbs). Once the control group started receiving the intervention, they experienced a mean weight loss of 1.8 kg (4 lbs), bringing the group closer to their baseline weight.

Results

Six systematic review articles and 24 intervention trials satisfied the inclusion and exclusion criteria and are included in this analysis. Among the 24 intervention studies, 12 of the studies were RCTs, 6 were non-randomized comparison trials, and 6 were pre-post outcome studies without a comparison group. The trials varied in terms of numbers of participants, intervention duration and design and study results; the 24 trials are summarized in *Table 2: Health Promotion Intervention Studies*.

Systematic Reviews

The research team identified six systematic reviews of literature related to health promotion interventions for people with SMI [54-59]. See *Table 1: Summary of Systematic Reviews*. The most recent review, by Veraeghe, et al. [54], evaluated aggregate data on effectiveness and the cost-effectiveness of lifestyle interventions for people with SMI. The authors identified 17 studies (14 trials, 3 reviews) meeting inclusion criteria for randomized outcome trials or systematic reviews of lifestyle interventions targeting physical activity and dietary habits in persons with SMI that had primary outcomes of changes in Body Mass Index and body weight. Of the 14 trials reviewed, interventions were associated with weight loss in 11 studies. The difference in weight loss between the intervention and control groups was statistically significant in nine studies. In aggregate, a total of 361 intervention participants ($N = 669$) had a mean weight loss of 1.96 kg (4.3 lbs) and a mean BMI decrease of 0.87 kg/m^2 . In addition, five studies reported improvements in quality of life and in general health, though none of the studies reported cost-effectiveness analyses [54]. Although statistically significant weight loss was found in the majority of studies, none of the studies achieved an overall clinically significant weight loss (5% or more) considered to be associated with reduced risk of serious physical health problems.

The authors conclude that it is “promising” that “small decreases” in body weight and BMI are possible for persons with SMI participating in health promotion interventions consisting of physical activity and dietary interventions. The authors also suggest that although mean changes are very modest, individual outliers may derive significant benefit.

Alvarez-Jimenez, et al. [56] examined ten non-pharmacologic health promotion RCTs with a total of 482 participants, including four studies aimed at preventing weight gain and six studies aimed at promoting weight loss. Both types of studies (preventing weight gain and promoting weight loss) had similar effects on mean body weight change. Alvarez-Jimenez, et al. [56] found a mean weight loss of 2.56 kg (5.6 lbs) and a mean BMI decrease of 0.91 kg/m^2 for the 253 intervention group participants ($N = 482$) in the 10 studies they reviewed. A comparison of group versus individual interventions found that studies evaluating individual interventions showed a trend for more benefit than group interventions, though the dif-

ference was not statistically significant. Adherence to weight management programs was more positively correlated with weight loss, suggesting that choice in modality should consider those more likely to engage participants in adherence to weight loss programs over time. Studies in this review ranged from an estimated 2.5% to 4.0% reduction in weight, with no interventions achieving a clinically significant threshold of reducing 5% of body weight.

Faulkner and colleagues [58] conducted a systematic Cochrane Collaborative review limited to RCTs to determine the effects of *both* pharmacological (excluding antipsychotic medication switching) and non-pharmacological strategies (diet/exercise) for reducing or preventing weight gain in people with schizophrenia [58]. This review identified 23 studies; however, only five of the studies were non-pharmacologic in nature. The authors concluded that non-pharmacological interventions were acceptable and feasible, but weight loss was modest and further research was recommended.

Lowe & Lubos [57] conducted a selective review that included eight studies with a total of 360 participants. This review identified two intervention categories: 1) four studies classified as psychoeducational interventions consisting of weight management dietary counseling, lifestyle coaching in group or individual discussions, or group-based cognitive behavioral therapy; and 2) four studies consisting of activity-based interventions consisting of combined exercise and dietary interventions. Significant limitations of the individual research studies were underscored including some studies having small sample sizes, high dropout rates, concurrent changes in medications, lack of control groups, etc. Overall, the authors conclude that there is limited evidence suggesting the effectiveness of either psychoeducational weight management interventions or activity-based combined exercise and dietary interventions.

Finally, the literature searches conducted by Cabassa et al. [55] and Loh et al. [59] were not as stringent in their exclusion criteria, both resulting in the retrieval of 23 studies, which varied widely in design. Loh and colleagues suggested that clinicians use health promotion programs as a preventative measure and noted that interventions with reward and/or reinforcement systems were most successful in producing weight loss. Cabassa et al. suggested that interventions should involve three components: exercise, nutrition, and general health promotion.

While the prior review papers were helpful to the research team in identifying review authors' findings and conclusions, the primary intent of examining prior review papers relating to health promotion programs for people with SMI was to ensure that the literature base of our review was comprehensive.

Table 1: Summary of Systematic Reviews

Author	Databases	Search terms	Inclusion	Exclusion	Primary/Final #
Verhaeghe et al., 2011 [54]	Medline, Web of Science, CINAHL, Cochrane Library	"mental disorders," or "severe mental illness," or "antipsychotic agents," AND "obesity," or "weight gain," or "weight," AND "lifestyle," or "intervention studies," or "food habits," or "physical activity," or "fruit," or "vegetables"	Studies examining effectiveness/cost of lifestyle interventions; adult participants w/ schizophrenia, schizoaffective disorder, depressive or bipolar disorder, or severe mental disorder; focus on changes in weight/BMI; applied psychoeducational and/or behavioral interventions on physical activity, eating habits.	Targeted general populations; primary outcome no change in weight/BMI; pharmacological intervention only.	913/17
Cabassa et al., 2010 [55]	Medline, PsycINFO, PubMed, Cochrane Collaboration	Combinations of: "schizophrenia," "schizoaffective disorder," "serious mental illness," "serious and persistent mental illness," "psychiatric disorders," "bipolar disorder," "depression," "obesity," "lifestyle intervention," "weight management," "weight management education," "cognitive-behavioral treatment," "physical activity," "exercise," "randomized controlled trial," "program evaluation," "case study"	Published between January 1980 and January 2010; written in English and conducted in the United States; report on physical health outcomes or health promotion outcomes of lifestyle interventions; population: adults diagnosed/classified with SMI.	<i>See inclusion.</i>	53/23
Alvarez-Jimenez et al., 2008 [56]	CENTRAL, Medline, EMBASE, PsycINFO, CINAHL, UMI, Proquest Digital Dissertations, SCI-EXPANDED, SSCI, A&HCI	"weight gain," "weight loss," "weight change," "body weight," AND "exercise," "psychoeducation," "intervention," "diet," "behavioural therapy," "cognitive therapy," "physical therapy," "group intervention," "management," AND "schizophrenia," or "psychosis"	"RCTs of a specific non-pharmacological adjunctive intervention aimed at preventing or controlling antipsychotic-induced weight gain;" at least 3/4 of participants diagnosed with schizophrenia-spectrum disorder; primary outcome of change in body weight and BMI.	No comparison group; no randomization; not enough information on sample characteristics; confirmation from authors that less than 3/4 sample not diagnosed with schizophrenia-spectrum disorder; 90% withdrawal rate; measurement of eating habits only; data not provided in usable format.	28/10

Author	Databases	Search terms	Inclusion	Exclusion	Primary/Final #
Lowe, T., & Lubos, E., 2008 [57]	CINAHL, BNI, PsycINFO, MEDLINE, Cochrane Database of Systematic Reviews	"exercise," "diet," "weight management," "weight gain," "schizophrenia"	Written in English; adult participants (16-65); schizophrenia/schizoaffective disorder treated with antipsychotic; improvement in weight profile; psychoeducational/dietary/exercise intervention; measureable outcomes of weight; papers within past 10 years.	Weight loss resulting from meds, surgery, other invasive intervention; outcome measures not specified; values used not universally recognized; unspecified diagnoses.	221/8
Faulkner et al., 2007 [58]	Cochrane Schizophrenia Group's Registry, MEDLINE, CINAHL, EMBASE, PsycINFO, UMI ProQuest Digital Dissertations, HealthSTAR, Sports Discus	"schizophrenia," "antipsychotic medication," "exercise," "intervention," "cognitive therapy," "behavioural therapy," "diet," "weight loss," "weight gain," "weight change," "weight," "physical therapy"	RCTs; population: people with schizophrenia or schizophrenia-like illness; weight loss or weight maintenance as primary outcome and goal; pharmacological and non-pharmacological.	Quasi-randomized; no comparison group; no usable data; not randomized; unclear diagnostic criteria.	NR/23 (5 non-pharma)
Loh et al., 2006 [59]	PsycINFO, Medline	"schizophrenia," "obesity," "weight," "weight loss," "weight gain," "prevention," "intervention," "antipsychotic," "cognitive," "behavioral," "behaviourial," "therapy," "exercise," "diet"	Written in English; peer reviewed journals; participants diagnosed/classified with schizophrenia or schizoaffective disorder; weight loss as outcome goal; weight loss assessed using standard measure.	<i>See inclusion.</i>	NR/23

NR = not reported

Health Promotion Study Descriptions

The research team identified 24 studies to include in this analysis. Twelve of the studies were RCTs; six studies included a comparison group but were not randomized; and six studies included only an intervention group without a control group. In two of the RCTs, the design consisted of a wait-list control group that received the intervention after the original intervention group, and the authors collected data for both groups [60, 61]. Although the research team excluded pharmacological-only interventions for weight loss, one RCT selected for this analysis compared a pharmacological weight loss intervention, a healthy lifestyle intervention, a combination of pharmacological and lifestyle interventions for weight loss, and a usual care control group [62]; the research team used the data related to the non-pharmacological components of the intervention in this review.

Intervention group sample sizes ranged from six participants at a single site to 314 participants across 49 sites, with an average intervention group size of 51.0 participants ($SD = 70.3$). Common inclusion criteria for study participants were as follows: adults; inpatients and/or outpatients of a psychiatric rehabilitation center; a DSM-IV diagnosis of schizophrenia, schizoaffective disorder, bipolar disorder, or other SMI; taking atypical antipsychotics for a predetermined length of time (e.g., at least three months); a significant increase in weight or BMI since beginning antipsychotic treatment; and obesity or a higher-than-average BMI (e.g., greater than 25 kg (55 lbs)/m²). Two studies also included a diagnosis of diabetes mellitus in their inclusion criteria [63, 64]. Potential participants commonly were excluded if they: had a severe medical condition (e.g., cardiovascular, neurological, neuromuscular, or endocrine disorder); had a weight loss contraindication (e.g., pregnancy, a thyroid disorder, anorexia nervosa); were in an acute psychotic episode; or had a substance abuse disorder. Mean participant age ranged from 26.3 to 53.1 years, with a median participant age among the studies of 42.1 years.[†] Mean baseline weight ranged from 64.7 kg (142.3 lbs) to 107.9 kg (237.4 lbs) (*median* = 93.5 kg, or 205.7 lbs), and mean baseline BMI ranged from 24.6 kg/m² to 39.3 kg/m² (*median* = 32.9 kg/m²).[‡]

Nineteen of 24 interventions in the studies selected for this analysis included a combination of nutrition- and exercise-based components [62-80]. Only four interventions focused primarily on nutrition [60, 61, 81, 82], and only one study contained an exercise-only intervention [83]. Nine of the studies used an education- or therapy-only approach to their intervention [61, 63, 64, 69-71, 74, 79, 81]; two of the study interventions utilized an activity with no education component [80, 83]; and 14 of the interventions used a combination education and activity approach [60, 62, 65-68, 72, 73, 75-78, 82].[§] See *Figure 1: Intervention Components*. Intervention durations ranged from 10 weeks [65, 67] to 18 months [75], with a mean of 20.2 weeks ($SD = 15.5$), and the research team is aware of eight studies included post-intervention follow-up measurements [61, 63, 67, 71, 72, 74, 81, 82, 84].

[†] Twenty-two of the 24 reports in the analysis reported on mean participant age.

[‡] Twenty-one of 24 reports included baseline weight and BMI information.

[§] For the purposes of this analysis, we describe interventions as activity-based or educational-/therapy-based based on the principle components of the design. For instance, if an intervention was aimed at promoting healthy eating habits through weekly group meetings, and participants were told to keep a food diary, we categorized it as educational-/therapy-based, and the food diary was considered part of the therapy and not a separate activity. Alternatively, if participants' diets were restricted to 1,300 calories and were assigned a personalized diet plan, for example, we considered that activity-based.

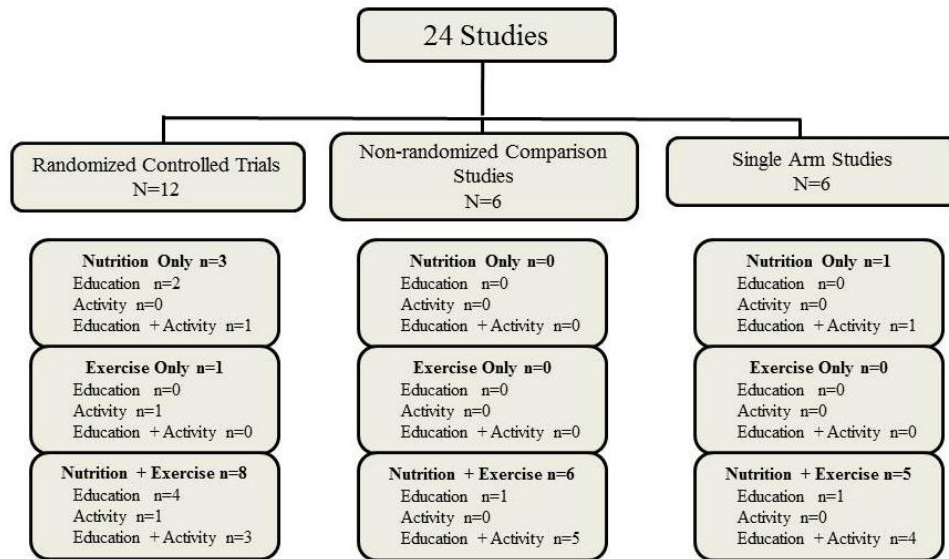


Figure 1: Intervention Components

Table 2: Health Promotion Intervention Studies

Author & Date	N (n)	Intervention Duration	Intervention Description	Educational or Therapy Sessions	Activity Sessions	Δ Weight (kg)			Δ BMI (kg/m2)		
<i>Randomized Controlled Trials</i>						Int.	Ctrl.	Diff.	Int.	Ctrl.	Diff.
Mauri et al., 2008 [60] ^a	33 (15)	12 weeks	Psychoeducational program consisting of weekly meetings with a food diary and assigned diet plan.	nutrition	diet	-3.6 ^f	+0.2 ^{NS}	3.8 ^f	-1.3 ^f	0.0 ^{NS}	1.3 ^f
Wu et al., 2008 [62] ^b	128 (32)	12 weeks	Four-arm combination of metformin and intervention: metformin alone, placebo alone, lifestyle intervention plus metformin, lifestyle intervention plus placebo. Lifestyle intervention included psychoeducational program, diet and exercise.	nutrition, exercise	diet, exercise	-1.3 ^d	+2.6 ^d	3.9 ^{NR}	-1.5 ^d	+0.9 ^d	2.4 ^{NR}
Jean-Baptiste et al., 2007 [61] ^a	18 (8)	16 weeks	Nutrition intervention based on the LEARN program with reimbursement for food provision. Exercise was also encouraged.	nutrition		-2.9 ^{NR}	+2.7 ^{NR}	5.6 ^d	-	-	-
Khazaal et al., 2007 [81]	61 (31)	12 weeks	Cognitive and behavioral treatment group sessions primarily focused on diet and nutrition with some exercise focus as well.	nutrition		-2.9 ^{NR}	-0.8 ^{NR}	2.1 ^{NR}	-1.4 ^{NR}	-0.2 ^{NR}	1.2 ^{NR}

Author & Date	N (n)	Intervention Duration	Intervention Description	Educational or Therapy Sessions	Activity Sessions	Δ Weight (kg)			Δ BMI (kg/m ²)		
Wu et al., 2007 [80]	53 (28)	6 months	Facility-based intervention consisted of a reduced calorie diet and exercise program.		diet, exercise	-4.2 ^d	+1.0 ^{NR}	5.2 ^d	-1.6 ^d	+0.4 ^{NR}	2.0 ^d
Kwon et al., 2006 [69]	48 (33)	12 weeks	Behavioral therapy consisting of nutritional and exercise education with self-monitoring through food and exercise diaries.	nutrition, exercise		-3.9 ^{NR}	-1.5 ^{NR}	2.4 ^f	-1.5 ^{NR}	-0.6 ^{NR}	0.9 ^f
McKibbin et al., 2006 [63]	64 (32)	24 weeks	Diabetes Awareness and Rehabilitation Training (DART) program involved diabetes education sessions related to nutrition and exercise.	diabetes, nutrition, exercise		-2.3 ^{NR}	+3.1 ^{NR}	5.4 ^d	-0.7 ^{NR}	+1.0 ^{NR}	1.7 ^d
Weber, M. & Wyne, K., 2006 [79]	15 (8)	16 weeks	Cognitive behavioral group intervention consisting of weekly sessions based on Diabetes Prevention Project modules.	nutrition, exercise		-2.5 ^{NR}	-0.6 ^{NR}	1.9 ^{NS}	-1.0 ^{NR}	-0.2 ^{NR}	1.0 ^{NS}
Beebe et al., 2005 [83]	12 (6)	16 weeks	Exercise-based intervention consisting of three weekly sessions of walking on treadmill.		exercise	-	-	-	-1.3 ^{NR}	-0.1 ^{NR}	1.2 ^{NS}

Author & Date	N (n)	Intervention Duration	Intervention Description	Educational or Therapy Sessions	Activity Sessions	Δ Weight (kg)			Δ BMI (kg/m2)		
Brar et al., 2005 [64]	72 (35)	14 weeks	Behavioral therapy consisting of a manualized educational program focusing on diet in the first weeks and exercise in later weeks.	nutrition, exercise		-2.3 ^{NR}	-1.1 ^{NR}	1.2 ^{NS}	-	-	-
Skrinar et al., 2005 [77]	20 (9)	12 weeks	Healthy Lifestyle intervention involving four weekly exercise sessions and one weekly seminar on nutrition and/or exercise.	nutrition, exercise	exercise	-2.2 ^{NR}	+1.2 ^{NR}	3.4 ^{NS}	-0.7 ^{NR}	+0.5 ^{NR}	1.2 ^{NS}
Littrell et al., 2003 [71]	70 (35)	16 weeks	Solutions to Wellness module-based psychoeducational classes with lessons focused on diet/nutrition and fitness/exercise.	nutrition, exercise		+0.4 ^{NS}	+3.3 ^d	2.9 ^e	+0.1 ^{NS}	+1.0 ^d	0.9 ^{NR}
<i>Non-randomized Comparison Studies</i>						Int.	Ctrl.	Diff.	Int.	Ctrl.	Diff.
Porsdal et al., 2010 [74]	373 (314)	12 weeks	"Solutions for Wellness" (SfW) program consisting of small group (4-8) sessions of lessons focused diet/nutrition, exercise selected from pre-determined subject manuals.	nutrition, exercise		-0.5 ^{NR}	+0.9 ^{NR}	1.4 ^{NR}	-	-	-

Author & Date	N (n)	Intervention Duration	Intervention Description	Educational or Therapy Sessions	Activity Sessions	Δ Weight (kg)			Δ BMI (kg/m2)		
Melamed et al., 2008 [72]	59 (28)	3 months	Facility-based with combination of nutritional counseling, group behavioral therapy, mealtimes overseen by supervisor, and walking sessions multiple times per week.	nutrition	nutrition, exercise	-	-	-	-2.8 ^{NR}	-0.2 ^{NR}	2.6 ^f
Poulin et al., 2007 [75]	110 (59)	18 months	Behavioral weight control program consisting of small group educational activity based on nutrition and exercise in combination with small group exercise sessions.	nutrition, exercise	exercise	-3.1 ^{NR}	+3.6 ^{NR}	6.7 ^f	-1.4 ^{NR}	+1.6 ^{NR}	3.0 ^f
Brown et al., 2006 [66]	36 (21)	12 weeks	Manualized psychiatric rehabilitation program with an individualized diet plan, weekly counseling sessions, dietary education, group sessions with goal setting/review, and exercise activity.	nutrition, exercise	nutrition, exercise	-2.7 ^{NR}	+0.5 ^{NR}	3.2 ^f	-1.0 ^{NR}	+0.2 ^{NR}	1.2 ^f
Menza et al., 2004 [73]	51 (31)	12 months	Healthy Living program consisting of nutrition counseling, exercise and behavioral interventions with group and individual components.	nutrition, exercise	limited exercise	-3.0 ^d	+3.2 ^{NR}	6.2 ^f	-1.7 ^g	+2.6 ^{NR}	4.3 ^f

Author & Date	N (n)	Intervention Duration	Intervention Description	Educational or Therapy Sessions	Activity Sessions	Δ Weight (kg)			Δ BMI (kg/m2)		
Ball et al., 2001 [65]	22 (11)	10 weeks	Weight Watchers 1-2-3 program consisting of weekly meetings plus a diet based on point-based food choice evaluation and supervised exercise sessions.	nutrition	diet, exercise	-2.3 ^{NR}	-0.2 ^{NR}	2.1 ^{NS}	-0.7 ^{NR}	-0.1 ^{NR}	0.6 ^{NS}
<i>Single Arm Studies</i>						Pre	Post	Diff.	Pre	Post	Diff.
Daumit et al., 2010 [68]	63	6 months	Facility-based with combination of counseling sessions and physical activity sessions, also kitchen staff educational sessions on healthier meals.	nutrition, exercise	exercise	95.7	93.6	-2.0 ^f	34.4	33.6	-0.8 ^f
Chen et al., 2009 [67]	33	10 weeks	"A Meaningful Day" program consisting of nutrition counseling along with exercise and behavioral interventions.	nutrition, lifestyle	exercise	78.8	76.7	-2.1 ^d	30.5	29.7	-0.8 ^d
Van Citters et al., 2009 [78] ^c	76	9 months	"In SHAPE" individualized intervention consisting of fitness/diet plans tailored to the individual, weekly meetings with health mentor, and fitness activities at local YMCA.	nutrition, exercise	exercise	91.9	93.0	- ^{NS}	32.9	33.4	- ^{NS}

Author & Date	N (n)	Intervention Duration	Intervention Description	Educational or Therapy Sessions	Activity Sessions	Δ Weight (kg)			Δ BMI (kg/m2)		
Lee et al., 2008 [70]	232	12 weeks	Group educational sessions focused on diet and exercise management consisting of weigh-in, self-monitoring, presentation and homework.	nutrition, exercise		-	-	-2.6 ^d	-	-	-1.0 ^d
Kalarchian et al., 2005 [82]	35	3 months	Diet intervention based on the Stoplight Diet with 12 hour-long educational sessions.	nutrition	diet	107.5	105.3	-2.2 ^d	36.5	35.7	-0.8 ^e
Richardson et al., 2005 [76]	39	18 weeks	Lifestyle intervention program consisting of nutrition and exercise education sessions plus a group walk at the end of each session.	nutrition, exercise	exercise	87.1	84.8	-2.3 ^g	-	-	-

^a Mauri et al. (2008) and Jean-Baptiste et al. (2007) used a method whereby two groups received the intervention, with a second group first serving as a control group. We report here on the initial phase of the intervention.

^b Wu et al. (2008) included four intervention groups. We report here on the “lifestyle intervention” group and the placebo group, which are comparable to the intervention and control groups in the other studies in this review.

^c The pre- and post- N-values in the study by Van Citters et al. (2009) vary, so the change from baseline to post-intervention cannot be determined.

^d Significant, $p \leq 0.001$

^e Significant, $p \leq 0.005$

^f Significant, $p \leq 0.01$

^g Significant, $p < 0.05$

^{NS} Not significant

^{NR} Significance not reported

Health Promotion Study Outcomes

Measures of physical health. Among the 24 studies selected for this review, intervention participants in 22 studies experienced an overall mean weight loss and/or decrease in BMI. See *Table 2: Health Promotion Intervention Studies*. In 19 trials, weight loss was reported *and* the research team was able to determine the percentage of weight lost by the intervention group. Among those studies, mean weight loss from baseline to intervention endpoint ranged from 0.5% to 5.4% (*median* = 2.6%).

Change in weight from baseline to the end of the intervention among the RCT intervention groups ranged from a slight gain of 0.4 kg (0.9 lbs) to a loss of 4.2 kg (9.2 lbs) (*median* = -2.5 kg, or -5.5 lbs). In comparison, weight change in the control groups ranged from a mean gain of 3.3 kg (7.3 lbs) to a mean loss of 1.5 kg (3.3 lbs) (*median* = +1.0 kg, or +2.2 lbs). Significant between-group weight change was reported in six RCTs [60, 61, 63, 69, 71, 80]. Among the five non-randomized comparison studies that reported on weight, intervention group weight change ranged from a loss of 0.5 kg (1.1 lbs) to a loss of 3.1 kg (6.8 lbs) (*median* = 2.7 kg, or 5.9 lbs), with the control groups experiencing mean weight changes ranging from a gain of 3.6 kg (7.9 lbs) to a loss of 0.2 kg (0.4 lbs) (*median* = +0.9 kg, or +2 lbs). The studies by Poulin et al. [75], Brown et al. [66] and Menza et al. [73] reported significant between-group weight change differences, with intervention groups uniformly presenting with a mean weight loss while the control groups gained weight overall. Finally, although intervention design, duration and the number of participants varied, the five single-arm studies that reported sufficient information to determine change in weight had similar weight loss results, ranging from a significant weight loss of 2.0 kg (4.4 lbs) to a significant loss of 2.6 kg (5.7 lbs) (*median* = 2.2 kg, or 4.8 lbs).

The research team examined those studies that reported intervention group weight loss by study design characteristics and intervention duration. For the studies that used a combined education and activity approach [60, 62, 65-68, 73, 75-77, 82] mean intervention group participant weight loss ranged from 1.3 kg (2.9 lbs) to 3.6 kg (7.9 lbs) (*median* = -2.3 kg, or -5.1 lbs). Significant mean weight change — either loss among intervention groups or differences between intervention and control groups — was achieved from baseline to endpoint in nine of the eleven studies. In the remaining studies [61, 63, 64, 69, 71, 74, 79-81], which used either an education-only or activity-only approach (and that reported mean intervention group weight loss), mean intervention group weight loss from baseline to endpoint ranged from 0.5 kg (1.1 lbs) to 4.2 kg (9.2 lbs) (*median* = -2.6 kg, or -5.7 lbs). Though the median weight loss was slightly greater among the intervention groups in those studies that primarily used either an educational or an activity-based intervention, 60% reported statistically significant weight loss or between-group weight change differences from baseline to endpoint, while 75% of combination studies reported statistically significant weight change findings. Of education-only studies, 56% reported statistically significant results relating to weight change.

In terms of intervention duration, the research team compared the mean weight loss of those studies with interventions of three months or shorter [60, 62, 65-67, 69, 70, 74, 77, 81, 82] to interventions that lasted longer than three months [61, 63, 64, 68, 73, 75, 76, 79, 80]. Among the shorter duration studies, mean intervention group weight loss ranged from 0.5 kg (1.1 lbs) to 3.9 kg (8.6 lbs) (*median* = -2.3 kg, or 5.1 lbs), and among the longer duration studies, mean weight loss ranged from a 2.0 kg (4.4 lbs) to 4.2 kg (9.2 lbs) (*median* = -2.5 kg, or -5.5 lbs). As one would expect, the interventions that were longer in

duration tended to produce more statistically significant results: seven of the 11 studies (64%) with the intervention lasting three months or less reported statistically significant between-group or pre-post weight loss, and eight of nine (89%) of the interventions lasting greater than three months reported significant mean intervention group weight loss or between-group results.

Eighteen studies reported a decrease in mean BMI among intervention group participants. Overall, the mean change in BMI from baseline to endpoint among the 18 intervention groups ranged from a slight increase of 0.1 kg/m² to a decrease of 2.8 kg/m² (*median* = -1.0 kg/m²). Mean intervention group BMI change for RCTs ranged from an increase of 0.1 kg/m² to a decrease of 1.6 kg/m² (*median* = -1.3 kg/m²), with significant BMI decreases reported in three RCTs [60, 62, 80]. Mean control group BMI change ranged from an increase of 1.0 kg/m² to a decrease of 0.6 kg/m² (*median* = +0.2 kg/m²), and four RCTs [60, 63, 69, 80] reported significant between-group differences in BMI change from baseline to endpoint. All of the studies that reported on BMI within the non-randomized comparison studies group reported a mean decline within the intervention group, ranging from a decrease of 0.7 kg/m² to a decrease of 2.8 kg/m² (*median* = -1.4 kg/m²). On the other hand, the control group means ranged from an increase of 2.6 kg/m² to a decrease of 0.2 kg/m² (*median* = +0.2 kg/m²). Between the intervention and control groups, four studies [66, 72, 73, 75] reported significant weight change differences from baseline to endpoint. Among the single-arm studies included in this review, three studies [67, 68, 82] reported a significant mean participant BMI decrease of 0.8 kg/m², and one study [70] reported a significant mean decrease of 1.0 kg/m².

Several studies included in our analysis measured and reported on additional physical health indicators, such as waist circumference, waist-to-hip ratio, and body fat percentage. Nine of the studies in this review (three RCTs [62, 63, 80], four non-randomized comparison studies [66, 73-75] and two single-arm studies [68, 78]) measured waist circumference at baseline and endpoint, and the research team could determine the mean change in waist circumference among the intervention group in eight studies. Mean change in waist circumference in those studies ranged from an increase of 0.1 cm to a decrease of 4.8 cm (*median* = -2.95 cm). Weber & Wyne [79] (*n* = 8) measured waist-to-hip ratio and found a mean 1.7% decrease among intervention group participants. Three studies measured body fat percentage and found a mean decreased body fat percentage among intervention participants. Intervention participants in the studies by Wu et al. [80] (*n* = 28), Beebe et al. [83] (*n* = 4) and Skrinar et al. [77] (*n* = 9) experienced an overall decrease in body fat of 1.3%, 3.7% and 0.7%, respectively.

Some authors used exercise performance and/or endurance measures as additional indicators of physical health. Daumit et al. [68], Beebe et al. [83] measured participants' 6-minute walking distance. In the study by Daumit et al., participants (*n* = 52) increased their walking distance by 104 feet, on average, from baseline to endpoint, and intervention participants in the Beebe et al. study (*n* = 4) increased their mean walking distance by nearly 153 feet. Skrinar et al. [77] gauged the performance time and exercise intensity of their study participants (*n* = 9), and found that from baseline to intervention endpoint, mean performance time decreased by 3.9%, while the intensity of exercise among study intervention participants increased by 5.2%. Van Citters et al. [78] looked at the level of physical activity of participants at baseline and follow-up (*n* = 57) using the Yale Physical Activity Scale (YPAS) and found significant increases in both overall level of physical activity and vigorous physical activity at study endpoint.

Psychological symptoms. Thirteen studies measured the psychological symptoms of participants at intervention baseline and endpoint, though one study used results only as covariates [63]. See *Table 3*. Overall, changes in general psychological symptoms and/or symptoms related to SMI were mixed and arguably negligible. Indeed, only four of ten studies reported significant improvement in intervention groups' general psychological symptoms or symptoms relating to SMI [60, 67, 75, 78]. Chen et al. [67] reported the most significant results, with a 22-point improvement on the Positive and Negative Symptoms Scale (PANSS) [85] among intervention participants. All of the studies reporting a significant improvement in the mental health status of their participants used a combined educational and activity design, whereas the design of the studies reporting insignificant results varied.

More than half of the studies that measured participants' depression and/or anxiety symptoms reported significant symptom improvement over the course of the study [67, 68, 76]. Participants in the Chen et al. [67] study experienced the most significant improvement in depression and anxiety symptoms. Interestingly, the three studies that reported significant results relating to depression scales were similar in design — combining exercise and nutrition as well as education and active participation.

Table 3: Psychological Symptoms Indicators

Author & Date	Scale Used	Scale Range/Description	Baseline Score (SD)		Post-Intervention Score (SD)		Diff.
General or Serious Mental Illness-Specific							
Porsdal et al., 2010 [74]	CGI-S [86]	0-7, with 0 being "normal" and 7 being "extremely ill"	NR		NR		-0.3 ^{NR}
Chen et al., 2009 [67]	PANSS [85]	30-210, with 30 indicating an absence of symptoms and 210 indicating and "extreme" presence of symptoms	72.2	(14.7)	50.2	(13.0)	-22.0 ^a
Van Citters et al., 2009 [78]	SF-12 MCS [87]	0-100, with higher scores indicating superior functionality	31.8	(12.9)	36.2	(13.4)	+4.4 ^d
	SANS [88]	1-5, with higher scores indicating presence of more severe negative symptoms	2.5	(0.7)	2.3	(0.6)	-0.2 ^d
Mauri et al., 2008 [60]	CGI-S, CGI-I [86]	0-7, with 0 being "normal" or "very much improved" and 7 being "extremely ill" or "very much worse," respectively	Significant improvement for the whole study sample during randomization phase of the study. ^d				
	GAF [89]	0-100, with higher scores indicating superior functionality	71.9		74.3		+2.4 ^d
Melamed et al., 2008 [72]	PANSS [85]	30-210, with 30 indicating an absence of symptoms and 210 indicating and "extreme" presence of symptoms	No significant improvement.				
Poulin et al., 2007 [75]	CGI-S, CGI-I [86]	0-7, with 0 being "normal" or "very much improved" and 7 being "extremely ill" or "very much worse," respectively	Mean CGI-S scores were significantly lowered from baseline to the end of the intervention, with the intervention group experiencing a greater decline. ^c				
Beebe et al., 2005 [83]	PANSS [85]	30-210, with 30 indicating an absence of symptoms and 210 indicating and "extreme" presence of symptoms	69.3		61.0		-8.3 ^{NS}
Brar et al., 2005 [64]	PANSS [85]	30-210, with 30 indicating an absence of symptoms and 210 indicating and "extreme" presence of symptoms	63.7	(17.4)	63.9	(22.6)	+0.2 ^{NS}
	CGI-S, CGI-C [86]	0-7, with 0 being "normal" or "very much improved" and 7 being "extremely ill" or "very much worse," respectively	Intervention group had a greater proportion of "much improved" and "very much improved" CGI-C ratings than the usual care group. ^{NS}				
Skrinar et al., 2005 [77]	SCL-90 [90]	5-point scales used, with higher scores indicating greater presence of symptoms.	NR		NR		-19.3 ^{NS}

Author & Date	Scale Used	Scale Range/Description	Baseline Score (SD)		Post-Intervention Score (SD)		Diff.
Ball et al., 2001 [65]	BPRS [91]	7-point scales used, with higher scores indicating greater presence/severity of symptoms.	29.1	(6.9)	31.0	(9.6)	+1.9 ^{NS}
	SANS [88]	6-point scales used, with higher scores indicating greater severity of negative psychiatric symptoms.	19.5	(5.9)	19.8	(8.6)	+0.3 ^{NS}
<i>Anxiety and Depression-Specific</i>							
Daumit et al., 2010 [68]	CES-D [92]	4-point scales used, with higher scores indicating presentation of more depression symptoms.	21.3	(12.5)	18.4	(13.4)	-2.9 ^c
Chen et al., 2009 [67]	BDI [93]	0-63, with higher scores indicating presentation of more depression symptoms.	20.2	(14.5)	14.1	(11.8)	-6.1 ^b
	BAI [94]	0-63, with higher scores indicating presentation of more severe anxiety symptoms.	18.5	(14.6)	12.4	(11.8)	-6.1 ^b
Van Citters et al., 2009 [78]	CES-D [92]	4-point scales used, with higher scores indicating presentation of more depression symptoms.	28.6	(13.0)	26.0	(15.4)	-- ^{NS}
Richardson et al., 2005 [76]	modified Brief CDS [95]	0-11, with higher scores indicating presentation of more depression symptoms.	5.7	(3.5)	3.4	(3.1)	-2.3 ^d
Ball et al., 2001 [65]	HAM-D [96]	Higher score indicates greater severity of depression.	7.4	(5.5)	6.8	(6.8)	-0.6 ^{NS}

NR = not reported

^a significant, $p < 0.001$

^b significant, $p < 0.005$

^c significant, $p < 0.01$

^d significant, $p < 0.05$

^{NS} not significant

^{NR} significance not reported

Quality of life. Ten studies included measures of quality of life or general health, and half of the studies that reported on these measures noted a significant improvement in either quality of life or general health from baseline to intervention endpoint [60, 67, 75, 77, 82]. See *Table 4*. Other than Chen et al. [67], who reported a significant improvement from baseline to endpoint in both quality of life and general health, only Mauri et al. [60] reported a significant improvement on a scale that specifically measured quality of life. However, only their second intervention group (which served as a control group during the first 12 weeks of the intervention) experienced an overall improvement in quality of life. Poulin et al. [75], Kalarchian et al. [82] and Skrinar [77] all used the 36-Item Short Form Health Survey (SF-36) [97], and reported significant mean improvements within the “General Health” subscale of the survey among intervention group participants.

Similar to psychological symptoms indicator results, all of the studies that reported significant improvements in quality of life or general health used a combined education and activity intervention design. In those studies that reported a significant improvement in the general health of intervention group participants [67, 75, 77, 82], the interventions incorporated both nutrition and exercise, although one study simply handed out pedometers to participants with a self-monitored goal of 10,000 steps per day [82].

Table 4: Quality of Life and General Health Indicators

Author & Date	Scale used	Scale Range Description	Baseline Score (SD)		Post-Intervention Score (SD)		Diff.
Daumit et al., 2010 [68]	Lehman QOL [98]	7-point scales, with higher score indicating higher quality of life.	4.9	(1.5)	4.8	(1.7)	-0.1 ^{NS}
	SF-36 [87] ^a	0-100, with a higher score indicating better health.	60.8	(23.9)	59.9	(28.0)	-0.9 ^{NS}
Porsdal et al., 2010 [74]	15D QOL [99]	Higher score indicates higher quality of life.	NR		NR		+0.0 ^{NS}
	SWN [100]	6-point scales, with higher score indicating higher subjective well-being.	NR		NR		+4.7 ^{NR}
Chen et al., 2009 [67]	WHO-QOL-BREF [101]	Higher score indicates higher quality of life.	76.4	(13.3)	84.7	(18.6)	+8.3 ^b
	SF-36 [87] ^a	0-100, with a higher score indicating better health.	42.9	(21.3)	50.5	(20.4)	+7.6 ^c
Van Citters et al., 2009 [78]	SF-12 PCS [87]	0-100, with a higher score indicating better health.	44.7	(12.5)	44.3	(11.1)	-- ^{NS}
Mauri et al., 2008 [60]	Q-LES-Q-SF [102]	Higher score indicates higher quality of life.	NR		NR		+2.7 ^d
Melamed et al., 2008 [72]	Q-LES-Q [102]	Higher score indicates higher quality of life.	3.3	(0.5)	3.6	(0.7)	+0.4 ^{NR}
Poulin et al., 2007 [75]	SF-36 [87]	0-100, with a higher score indicating better health.	Physical health improved for intervention group. ^d				
Kalarchian et al., 2005 [82]	SF-36 [87] ^a	0-100, with a higher score indicating better health.	Significantly improved general health and physical functioning, and marginally improved energy and social functioning. ^d				
Kwon et al., 2005 [69]	WHO-QOL-BREF [101]	Higher score indicates higher quality of life.	NR		NR		+1.1 ^{e; NR}
Skrinar et al., 2005 [77]	Lehman QOL [98]	7-point scales, with higher score indicating higher quality of life.	NR		NR		+0.7 ^{NS}
	SF-36 [87] ^a	0-100, with a higher score indicating better health.	NR		NR		+13.6 ^d

NR= not reported

^a Reported several subscales; used "General Health" subscale for the purposes of this table.^b Significant, $p < 0.005$ ^c Significant, $p < 0.01$ ^d Significant, $p < 0.05$ ^e Reported on physical well-being only.^{NS} Not significant^{NR} Significance not reported

Self-efficacy. Only four studies [63, 64, 68, 78] selected for this review included some measure of participant self-efficacy, and just two of those studies reported significant results. McKibbin et al. [63] measured self-efficacy using a diabetes-specific efficacy scale with three sub-scales and found between-group significance among the three scales: psychosocial aspects ($p < 0.01$), readiness to change ($p < 0.01$) and setting/achieving goals ($p < 0.001$). Brar et al. [64] used the Client Satisfaction Questionnaire (CSQ-8) [103] to assess participant self-efficacy. The authors found a significant improvement in CSQ-8 scores among the intervention group from baseline to intervention endpoint ($p = 0.15$) and a significant between-group disparity at endpoint ($p = 0.004$).

In addition to formal measures of participant self-efficacy, the research team looked at follow-up results as potential indicators of efficacy. For the most part, intervention groups tended to lose small quantities of weight or at least maintain their original weight loss after the intervention as control groups continued to gain weight.

Four RCTs reported on intervention follow-up results to assess, if results were maintained following termination of the intervention. Khazaal et al. [81] conducted follow-up assessments three months after the end of their intervention and found slight mean weight loss (-0.6 kg, or -1.3 lbs) among intervention group participants and a further weight gain (+2.5 kg, or +5.5 lbs) among the control group participants. Jean-Baptiste et al. [61] also conducted a follow up, and found that the 12 participants who completed the follow-up measures had lost an additional mean 1.8 kg (4 lbs). McKibbin et al. [84] completed follow-up measurements one year after baseline and six months after the end of the intervention, finding that intervention participants continued to experience a decrease in BMI after the intervention had concluded. At a six-month follow up, Littrell et al. [71] observed a continuing mean weight gain by the control group while the intervention group lost a small amount of weight from the intervention endpoint, resulting in a significant ($p < 0.001$) weight change discrepancy between the groups from baseline to follow-up.

Two non-randomized controlled studies reported similar discrepancies between study groups at follow-up. Porsdal et al. [74] conducted a follow-up three months after the end of their three-month intervention, and the mean weight for the Solutions for Wellness intervention group decreased by 0.2 kg (0.4 lbs). Melamed et al. [72] followed up with their intervention and control group participants at one year and found that the intervention group's mean BMI decreased by 0.3 kg/m²; meanwhile, the control group's mean BMI increased by 0.7 kg/m².

Two studies without control groups performed follow-up measurements. Chen et al. [67] followed up with study participants at weeks 12, 24 and 48 following the commencement of their 10-week intervention. At weeks 12 and 24, participants had lost 1.0 kg (2.2 lbs) and 0.7 kg (1.5 lbs), respectively. At week 48, over 60% of participants were available for follow-up, and although those participants had gained a mean weight of 1.1 kg (2.4 lbs), their final weights nevertheless represented a significant ($p < 0.001$) mean loss from baseline. Kalarchian et al. [82] also conducted three post-intervention follow-ups — at three months, six months and nine months after the intervention. A year after the end of the intervention, the study group's weight had remained relatively stable, first declining by a mean 0.8 kg (1.8 lbs) at three months and increasing by 0.4 kg (0.9 lbs) and 0.1 kg (0.2 lbs) at months six and twelve, respectively.

Summary of Findings

What are the findings of prior reviews of the effectiveness of non-pharmacological lifestyle interventions for overweight persons with SMI?

Among the six systematic reviews evaluated, *statistically* significant weight loss was found in the majority of studies reviewed of non-pharmacological lifestyle interventions targeting physical activity and dietary habits in persons with SMI. At the same time, none of the reviews identified a high-quality study finding an overall (mean) *clinically* significant weight loss of 5% more of body weight considered to be associated with reduced risk of serious physical health problems. In addition, a small number of reviewed studies reported improvements in quality of life and in general health, though none of the studies reported cost-effectiveness analyses.

Findings of This Comprehensive Review

This comprehensive and current review evaluated the characteristics and outcomes of randomized trials (RCTs) *as well as* high quality non-randomized trials and well-designed pre-post outcome studies. Evaluations of overall effectiveness in weight loss used median (rather than mean or average) weight loss to minimize the effect of outliers. In addition, this review examined each study to identify characteristics associated with better outcomes including intervention duration, education and/or activity based interventions, and the use of diet and/or exercise.

What is the overall effectiveness of non-pharmacological lifestyle interventions in achieving weight loss among overweight individuals with SMI?

Among the 24 studies selected for our review, intervention participants in 22 studies (92% of studies reviewed) experienced an overall mean weight loss and/or decrease in BMI. **Mean weight loss achieved for the interventions studied in the RCT studies consisted of a median 2.5 kg (5.5 lbs).** All of the controlled studies reported differences in weight and/or BMI change between the intervention and control groups, and those differences were statistically significant in 10 of the controlled studies.

Percentage of total body weight loss was reported (or able to be calculated) in 19 of the research trials, with a median of 2.6%. Only one of the trials achieved an overall clinically significant weight loss of 5% or greater [80]; however, this mean group weight loss was achieved in a facility-based context and has limited application for community-based intervention. Furthermore, it is important to note that overall weight loss for the total study sample does not indicate success rates for individual participants. For example, one of the studies reported that almost two-fifths of participants (38%) lost at least 5% of their baseline weight [63].

In summary, lifestyle interventions appear to be successful in achieving clinically significant weight loss for a subgroup of participants, but further enhancements will be needed in order to achieve an *overall* clinically significant weight loss.

What is the overall effectiveness of physical exercise interventions in improving fitness among individuals with SMI who are overweight?

In general, clinically significant increases in physical fitness and activity level (as measured by the 6-minute walk test and the YPAS (Yale Physical Activity Scale) were achieved in several of the interventions that focused on providing active and intensive physical exercise programs.

Do longer interventions achieve better results?

Interventions that were longer in duration tended to produce more statistically significant results: eight of nine (89%) of the interventions lasting greater than three months reported significant mean intervention group weight loss or between-group results. In contrast, seven of the eleven studies (64%) with the intervention lasting three months or less reported statistically significant between-group or pre-post weight loss. Of importance, longer compared to shorter program duration was associated with greater overall change. In general, programs of three months or less in duration reported smaller changes.

Are general wellness education programs successful?

Programs that incorporated a more non-specific wellness education approach were generally *not* successful in achieving results. Among education only programs, just over half (56%) achieved statically significant differences in weight lost or intervention-control group weight change comparison from baseline to endpoint. In general, educational programs with significant findings incorporated a focus on weight management (e.g., keeping a food diary, physical activity diary and monitoring weight).

Do combined education and activity-based programs work better than education alone?

Statistically significant health benefits were reported more frequently among the interventions that utilized a combined educational- and activity-based approach than among those that used one or the other alone. Nine of twelve (75%) of studies using a combined approach of education and activity achieved statistically significant weight loss or between-group weight change from baseline to endpoint. The one program consisting only of activity also achieved statistically significant weight loss.

Do combined physical activity programs result in improved psychological symptoms and quality of life for persons with SMI?

Although over half of the studies measured psychological symptom outcomes such as depression and anxiety, only three of the studies resulted in significant improvement. Of note, the three studies that reported significant results relating to depression were similar in design – combining exercise and nutrition as well as education and active participation. In general, lifestyle interventions demonstrated improved psychological functioning of people with SMI: over half of the studies that measured depression symptoms reported statistically significant symptomatic improvement from the beginning until the end of the intervention among program participants.

Similarly, all of the studies that reported significant improvements in quality of life or general health used a combined education and activity intervention design.

Summary Recommendations

This comprehensive review on the effectiveness of physical activity and nutrition interventions for persons with serious mental illness underscores the limitations of existing research literature with respect to the size and quality and the modest magnitude of the results with respect to effectiveness. Considering these limitations, this review suggests the following summary recommendations:

- Lifestyle health promotion programs of longer duration (3 or more months) consisting of a manualized, combined education- and activity-based approach, and incorporating both nutrition and physical exercise are likely to be the most effective in reducing weight, improving physical fitness and improving psychological symptoms and overall health.
- Programs that are less likely to be successful include briefer duration interventions, general wellness or health promotion or education-only programs, non-intensive, unstructured, or nonmanualized interventions and programs limited to nutrition only or exercise only (as opposed to combined nutrition and exercise).
- If weight loss is a primary goal, the nutritional component is critical and is more likely to be successful if it incorporates active weight management (i.e., participant and program monitoring of weights and food diaries), as opposed to nutrition education alone.
- If physical fitness is a primary goal, activity based programs that provide active and intensive exercise and measurement of fitness (e.g., 6-minute walk test or standardized physical activity monitoring) are more likely to be successful, in contrast to programs solely providing education, encouragement or support for engaging in physical activity.
- Evidence-based health promotion consisting of combined physical fitness and nutrition programs should be an integral component of mental health services seeking to provide overall wellness and recovery for persons with SMI.
- Lifestyle behaviors (nutrition, physical activity, tobacco use), physical fitness and weight outcomes, as well as evidence-based program fidelity, should be objectively and reliably measured and monitored both as a component of providing effective health promotion programming *and* as core indicator of quality mental health services.

Further research is warranted in numerous areas including: approaches to improve the magnitude of fitness and weight loss improvement; individual tailoring of interventions to improve outcomes; the role and impact of peer support; sustainability of individual outcomes over time; cost effectiveness and sustainable financial models for integrated health promotion; use of remote monitoring and telehealth technology to improve and measure outcomes; use of incentives and vouchers for participation and outcomes in nutrition, fitness and weight-loss programs; combined health promotion and pharmacological interventions; and successful approaches to implementation and dissemination of promising and evidence-base health promotion practices.

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